NDA 16-812/S-029

Parkedale Pharmaceuticals, Inc. MAR 14 2000
501 Fifth Street
Bristol, Tennessee 37620

Attention: Thomas K. Rogers, III
Vice President, Regulatory Affairs

Dear Mr.Rogers:

Please refer to your supplemental new drug application dated September 15, 1999, received September 17, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ketalar (ketamine hydrochloride) Injection, 10 mg/mL, 50 mg/mL, and 100 mg/mL.

This "Changes Being Effected - supplemental new drug application provides for changes in the vial and carton labeling in order to more distinctly identifiy the product and strength for each of the three presentations.

We have completed the review of this supplemental application, and it is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Judit Milstein, Regulatory Project Manager, at (301) 827-7410.

Sincerely,

Cy thia G. McCormick M.D.
Director
Division of Anesthetic, Critical Care, and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

NDC 61570-581-02

STERI-VIAL®

# Ketalar®

(Ketamine HCl Inj, USP)

200 mg per 20 mL*
(10 mg/mL)

℞ Only

20 mL

Monarch Pharmaceuticals®

*Each mL contains Ketamine Hydrochloride equivalent to 10 mg of ketamine with a pH range of 3.5–5.5.
Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if precipitate appears.
**Store at controlled room temperature 15°–30°C (59°–86°F). Protect from light. For slow intravenous or intramuscular use.**
Contains not more than 0.1 mg/mL benzethonium chloride added as a preservative.
**Usual Dosage**—See package insert.
Manufactured for:
Monarch Pharmaceuticals, Inc.
Bristol, TN 37620
By: Parkedale Pharmaceuticals, Inc.
Rochester, MI 48307

581G011

NDC 61570-582-01

STERI-VIAL®

# Ketalar®

(Ketamine HCl Inj, USP)

**500 mg per 10 mL*
(50 mg/mL)**

℞ Only

**10 mL**

Monarch Pharmaceuticals®

*Each mL contains Ketamine Hydrochloride equivalent to 50 mg of ketamine with a pH range of 3.5–5.5.
Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if precipitate appears.
**Store at controlled room temperature 15°–30°C (59°–86°F). Protect from light.**
**For slow intravenous or intramuscular use.**
Contains not more than 0.1 mg/mL benzethonium chloride added as a preservative.
**Usual Dosage**—See package insert.

Manufactured for:
Monarch Pharmaceuticals, Inc.
Bristol, TN 37620
By: Parkedale Pharmaceuticals, Inc.
Rochester, MI 48307

NDC 61570-585-05

STERI-VIAL®

# Ketalar®

(Ketamine HCl Inj, USP)

CONCENTRATE
500 mg per 5 mL*
(100 mg/mL)

℞ Only

5 mL

Monarch Pharmaceuticals®

**MUST BE DILUTED PRIOR TO IV USE.**

*Each mL contains Ketamine Hydrochloride equivalent to 100 mg of ketamine with a pH range of 3.5–5.5. Color of solution may vary from colorless to very slightly yellowish and may darken upon prolonged exposure to light. This darkening does not affect potency. Do not use if precipitate appears.

**Store at controlled room temperature 15°–30°C (59°–86°F). Protect from light.**

**For IM/slow IV use. Must dilute prior to IV use.**

Contains not more than 0.1 mg/mL benzethonium chloride added as a preservative.

**Usual Dosage**–See package insert.

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Bristol, TN 37620
By: Parkedale Pharmaceuticals, Inc.
Rochester, MI 48307